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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No. 09/754,853	Applicant(s) HAUGE ET AL.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-77* is/are pending in the application.

4a) Of the above claim(s) *76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-75 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 1/2,
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *5,6 & 10* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-10 and SEQ ID NO: 2, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the restriction requirement is an undue division of Applicant's invention into an inordinately high number of allegedly independent and distinct inventions (page 1 of the Response). Applicant has also traverses the election of a single nucleic acid sequence because it places an economic barrier between inventors and their exclusive rights (page 2 of the Remarks). This is not found persuasive because each of the methods are directed to identifying distinct features of a soybean plant, in addition the isolated nucleic acids and transgenic plants are patentably distinct compositions of matter under 35 USC § 121. In addition, the nucleic acid sequences disclosed by Applicant are inordinately long. Applicant's SEQ ID NO: 2, for example, requires more than a week of computer time to search its entire sequence using the extensive database at the Patent Office, hence searching more than one sequence would be even more burdensome. Finally, Applicant has cancelled the pending claims and submitted new claims more limited to the elected invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-72 have been cancelled and new claims 73-77 have been added as requested in the Response filed 7 October 2002, as Paper No. 11.

3. Claim 76 is withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11. Claim 76 is directed to a non-elected nucleic acid sequence and non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

5. This application contains claim 76 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.

Information Disclosure Statement

6. The information disclosure statements filed 19 November 2001, 15 January 2002 and 16 September 2002 have been considered, signed copies of which are attached hereto. Reference AF, International Search Report for PCT/US01/00552, in the IDS filed 19 November 2001 has been considered but will not be published on the face of the patent.

Specification

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 57, lines 2 and 3. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Drawings

8. The Draftsman has approved the drawing.

Claim Objections

9. Claims 74, 75 and 77 are objected to because of the following informalities: The phrase "A method" should read -- The method -- in referring to claim 73. Appropriate correction is required.

10. Claims 73 and 74 are objected to as being directed to non-elected subject matter. The claims will be examined to the extent that they read upon the elected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 73-75 and 77 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method for the production of a soybean plant having an SCN resistance comprising screening a population for a member with a nucleic acid molecule having at least 15 nucleotides capable of specifically hybridizing at least under low

stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 or a complement thereof.

Applicant describes a nucleic acid molecule having the sequence of SEQ ID NO: 2 that segregates with an *rhg*1 SCN resistance allele.

Applicant does not describe what the nucleic acid molecule having at least 15 nucleotides capable of specifically hybridizing at least under low stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 or a complement thereof is.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself".

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

13. Claims 73-75 and 77 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a method for the production of a soybean plant having an SCN resistance comprising screening a population for a member with a nucleic acid molecule having at least 15 nucleotides capable of specifically hybridizing at least under low stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 or a complement thereof.

Applicant teaches a nucleic acid molecule, having the sequence of SEQ ID NO: 2, which segregates with an *rhg*1 SCN resistance allele.

Applicant does not teach what the nucleic acid molecule having at least 15 nucleotides capable of specifically hybridizing at least under low stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 or a complement thereof is.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for what nucleic acid molecule having at least 15 nucleotides capable of specifically hybridizing at least under low stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 or a complement thereof can be used to practice the claimed method. The art teaches that identifying DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe or sequence of interest. Fourgoux-Nicol *et al* (1999, Plant Molecular Biology 40: 857-872) teach the identification of a 674bp fragment using a 497bp probe incorporating stringent hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65^0C (page 859, left column, 2^{nd} paragraph). Fourgoux-Nicol *et al* also teach that the probe and identified DNA fragment exhibited a number of sequence differences comprising a 99bp insertion within the probe and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2). In the present example, it is unclear what level of identity the "at least 15 nucleotides" has with the nucleotide sequence of SEQ ID NO: 2. In addition, the art teaches that the same size band amplified across populations does not necessarily mean that bands possess the same sequence unless proven by hybridization studies (see Staub and Serquen 1996, HortScience 31(5):729-738, specifically page 731, right column). Hence, it would have required undue trial and error

experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of nucleic acid molecules having at least 15 nucleotides that are capable of specifically hybridizing at least under low stringency conditions to a nucleic acid molecule that has a sequence located on SEQ ID NO: 2 that would allow for selection of a SCN resistant soybean in a reasonably predictable manner.

14. Claim 74 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. If each of the soybean varieties listed in claim 74 is publicly available, then a statement on the record to that fact would obviate this rejection. The examiner notes that arbitrary varietal designations such as "Jack" may or may not be enabled even if a "Jack" soybean variety is publicly available. If each of the soybean varieties is not publicly available then the requirement for deposit of biological material must be perfected in order to enable the claimed invention.

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,

(v) the deposit will be replaced if it should ever become inviable.

15. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

16. Claims 73-75 and 77 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 73, the claimed method is in general indefinite. At step (A), the crossing step comprises crossing a first soybean having at least one rhg1 SCN resistance allele or an Rhg4 resistance allele, yet at step (B) one screens for both alleles. Hence, it is unclear what the metes and bounds of the claimed method are.

At claim 73 step (B), line 3, the phrase "specifically hybridizing at least under low stringency conditions" is indefinite and appears to be an oxymoron. It is unclear how one could have a nucleic acid molecule hybridize "specifically" under "low stringency conditions". Hence, it is unclear what the metes and bounds of the claimed invention are.

At claim 73 step (B), subsections (i) and (ii), the phrase "and is linked to said..." is indefinite because it is unclear if this limitation is referring to the second nucleic acid molecule of the subsection or the first nucleic acid molecule having at least 15 nucleotides. Hence, it is unclear what the metes and bounds of the claimed invention are.

At claim 73, (B)(ii), lines 2-3, the phrase "said RHG4 SCN resistant allele" lacks proper antecedent basis within the claim.

At claim 73, step (C), said selecting step is indefinite because it is unclear if there are missing, further method steps not recited in the claim; this appears to be an intended use limitation and does not clearly designate that "a soybean having an SCN resistance" is selected as stated in the preamble of the claim. Hence, it is unclear what the metes and bounds of the claimed method are.

At claims 73 and 75, the phrase "is capable of specifically hybridizing" is indefinite because this phrase does not recite a definite feature of the claimed method and thus it is unclear what the metes and bounds of the claims are.

Claim 74 is indefinite because said claim contains two Markush groups linked using the definitive conjunction "and" while claim 73 to which it is dependent clearly uses the alternative conjunction "or" in referring to the first soybean plant having an SCN resistant allele. In addition, said claim is in improper Markush format, for example, at lines 6-7, the phrase "and Doles and SCN resistant progeny thereof" is improper; the phrase -- and Doles, or SCN resistant progeny thereof, -- is suggested. See MPEP 2173.05(h).

At claim 74, line 10, the phrase "an Rhg4 SCN resistant allele" lacks proper antecedent basis in claim 73. Appropriate correction is required.

Claim 74 is indefinite because the sole designation of a plant by its breeding line name or number is arbitrary and creates ambiguity in the claims. For example, the plant disclosed in this application could be designated by some other arbitrary means, or the assignment of the breeding line name could be arbitrarily changed to designate another plant. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F .2d 1378, 1382; 166 USPQ 204,

208 (CCPA 1970). Amendment of the claim to refer to the deposit accession number of the claimed breeding line would obviate this rejection.

At claim 77, line 3, the phrase "an Rhg4 SCN resistant allele" lacks proper antecedent basis in claim 73. Appropriate correction is required.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

18. Claims 73, 74, 75 and 77 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lightfoot *et al* (US Patent 6,300,541 B1, filed 14 January 1997).

Lightfoot discloses a method for producing a soybean plant having an SCN resistance comprising crossing a first soybean plant having an *rhg*1 SCN resistant allele, soybean variety 'Jack' for instance, and screening a segregated population to select a resistant progeny with a nucleic acid molecule having at least 15 nucleotides which are capable of "specifically" hybridizing at least under low stringency conditions to a sequence located on Applicant's SEQ ID NO: 2 or complements thereof, and is linked to said *rhg*1 SCN resistant allele (see claims 1-3, specifically markers $O103_{512}$ and SATT39). Lightfoot discloses that the $O103_{512}$ and SATT39 markers are linked to the

*rhg*1 SCN resistant allele (see figure 23). Lightfoot also discloses a method using the parental soybean variety 'Hartwig' which comprises the Rhg4 SCN resistant allele in Example 8 at columns 32-35 and said method using parental soybean varieties comprising both the rhg1 SCN resistance allele and the Rhg4 SCN resistance allele at column 33, lines 30-35. Hence, Lightfoot has previously disclosed all of the claim limitations.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~160~~ 1638

David H. Kruse, Ph.D.
6 December 2002